

## Food and Drug Administration, HHS

## § 807.3

in accordance with part 20 of this chapter.

(b) Before public disclosure of a report, FDA will delete from the report:

(1) Any information that constitutes trade secret or confidential commercial or financial information under § 20.61 of this chapter; and

(2) Any personnel, medical, or similar information, including the serial numbers of implanted devices, which would constitute a clearly unwarranted invasion of personal privacy under § 20.63 of this chapter or 5 U.S.C. 552(b)(6); provided, that except for the information under § 20.61 of this chapter or 5 U.S.C. 552(b)(4), FDA will disclose to a patient who requests a report all the information in the report concerning that patient.

### PART 807—ESTABLISHMENT REGISTRATION AND DEVICE LISTING FOR MANUFACTURERS AND INITIAL IMPORTERS OF DEVICES

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#### Subpart A—General Provisions

##### § 807.3 Definitions.

(a) *Act* means the Federal Food, Drug, and Cosmetic Act.

(b) *Commercial distribution* means any distribution of a device intended for human use which is held or offered for sale but does not include the following:

(1) Internal or interplant transfer of a device between establishments within the same parent, subsidiary, and/or affiliate company;

(2) Any distribution of a device intended for human use which has in effect an approved exemption for investigational use under section 520(g) of the act and part 812 of this chapter;

(3) Any distribution of a device, before the effective date of part 812 of this chapter, that was not introduced or delivered for introduction into interstate commerce for commercial distribution before May 28, 1976, and that is classified into class III under section

513(f) of the act: *Provided*, That the device is intended solely for investigational use, and under section 501(f)(2)(A) of the act the device is not required to have an approved pre-market approval application as provided in section 515 of the act; or

(4) For foreign establishments, the distribution of any device that is neither imported nor offered for import into the United States.

(c) *Establishment* means a place of business under one management at one general physical location at which a device is manufactured, assembled, or otherwise processed.

(d) *Manufacture, preparation, propagation, compounding, assembly, or processing* of a device means the making by chemical, physical, biological, or other procedures of any article that meets the definition of device in section 201(h) of the act. These terms include the following activities:

(1) Repackaging or otherwise changing the container, wrapper, or labeling of any device package in furtherance of the distribution of the device from the original place of manufacture to the person who makes final delivery or sale to the ultimate consumer;

(2) Initial importation of devices manufactured in foreign establishments; or

(3) Initiation of specifications for devices that are manufactured by a second party for subsequent commercial distribution by the person initiating specifications.

(e) *Official correspondent* means the person designated by the owner or operator of an establishment as responsible for the following:

(1) The annual registration of the establishment;

(2) Contact with the Food and Drug Administration for device listing;

(3) Maintenance and submission of a current list of officers and directors to the Food and Drug Administration upon the request of the Commissioner; and

(4) The receipt of pertinent correspondence from the Food and Drug Administration directed to and involving the owner or operator and/or any of the firm's establishments.

(f) *Owner or operator* means the corporation, subsidiary, affiliated com-

pany, partnership, or proprietor directly responsible for the activities of the registering establishment.

(g) *Initial importer* means any importer who furthers the marketing of a device from a foreign manufacturer to the person who makes the final delivery or sale of the device to the ultimate consumer or user, but does not repackage, or otherwise change the container, wrapper, or labeling of the device or device package.

(h) Any term defined in section 201 of the act shall have that meaning.

(i) *Restricted device* means a device for which a requirement restricting sale, distribution, or use has been established by a regulation issued under section 520(e) of the act, by order as a condition of premarket approval under section 515(d)(1)(B)(ii) of the act, or by a performance standard issued in accordance with sections 514(a)(2)(B)(v) and 514(b) of the act.

(j) *Classification name* means the term used by the Food and Drug Administration and its classification panels to describe a device or class of devices for purposes of classifying devices under section 513 of the act.

(k) *Product code* means the code used by FDA to identify the generic category of a device.

(l) *Representative sampling of advertisements* means typical advertising material that gives the promotional claims made for the device.

(m) *Representative sampling of any other labeling* means typical labeling material (excluding labels and package inserts) that gives the promotional claims made for the device.

(n) *Material change* includes any change or modification in the labeling or advertisements that affects the identity or safety and effectiveness of the device. These changes may include, but are not limited to, changes in the common or usual or proprietary name, declared ingredients or components, intended use, contraindications, warnings, or instructions for use. Changes that are not material may include graphic layouts, grammar, or correction of typographical errors which do not change the content of the labeling, changes in lot number, and, for devices where the biological activity or known

composition differs with each lot produced, the labeling containing the actual values for each lot.

(o) *510(k) summary* (summary of any information respecting safety and effectiveness) means a summary, submitted under section 513(i) of the act, of the safety and effectiveness information contained in a premarket notification submission upon which a determination of substantial equivalence can be based. Safety and effectiveness information refers to safety and effectiveness data and information supporting a finding of substantial equivalence, including all adverse safety and effectiveness information.

(p) *510(k) statement* means a statement, made under section 513(i) of the act, asserting that all information in a premarket notification submission regarding safety and effectiveness will be made available within 30 days of request by any person if the device described in the premarket notification submission is determined to be substantially equivalent. The information to be made available will be a duplicate of the premarket notification submission, including any adverse safety and effectiveness information, but excluding all patient identifiers, and trade secret or confidential commercial information, as defined in §20.61 of this chapter.

(q) *Class III certification* means a certification that the submitter of the 510(k) has conducted a reasonable search of all known information about the class III device and other similar, legally marketed devices.

(r) *Class III summary* means a summary of the types of safety and effectiveness problems associated with the type of device being compared and a citation to the information upon which the summary is based. The summary must be comprehensive and describe the problems to which the type of device is susceptible and the causes of such problems.

(s) *United States agent* means a person residing or maintaining a place of business in the United States whom a foreign establishment designates as its agent. This definition excludes mailboxes, answering machines or services, or other places where an individual

acting as the foreign establishment's agent is not physically present.

(t) *Wholesale distributor* means any person (other than the manufacturer or the initial importer) who distributes a device from the original place of manufacture to the person who makes the final delivery or sale of the device to the ultimate consumer or user.

(u) *Fiscal year* means the FDA fiscal year, which runs from October 1 through September 30.

(v) *FURLS* means the Food and Drug Administration's Unified

Registration and Listing System.

(w) *FDA premarket submission number* means the number assigned by FDA to a premarket device submission, such as a Premarket Approval Application (PMA); Humanitarian Device Exemption (HDE); New Drug Application (NDA); Biologics License Application (BLA); de novo classification petition; or Premarket Notification (510(k)).

(x) *Importer* means, for purposes of this part, a company or individual in the United States that is an owner, consignee, or recipient, even if not the initial owner, consignee, or recipient, of the foreign establishment's device that is imported into the United States. An importer does not include the consumer or patient who ultimately purchases, receives, or uses the device, unless the foreign establishment ships the device directly to the consumer or patient.

(y) *Person who imports or offers for import* means, for purposes of this part, an agent, broker, or other entity, other than a carrier, that the foreign establishment uses to facilitate the import of its device into the United States.

[42 FR 42526, Aug. 23, 1977, as amended at 43 FR 37997, Aug. 25, 1978; 57 FR 18066, Apr. 28, 1992; 58 FR 46522, Sept. 1, 1993; 59 FR 64295, Dec. 14, 1994; 60 FR 63606, Dec. 11, 1995; 63 FR 51826, Sept. 29, 1998; 66 FR 59159, Nov. 27, 2001; 77 FR 45940, Aug. 2, 2012]

## Subpart B—Procedures for Device Establishments

### § 807.20 Who must register and submit a device list?

(a) An owner or operator of an establishment not exempt under section 510(g) of the Federal Food, Drug, and Cosmetic Act or subpart D of this part